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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,466	07/18/2003	Gary S. Dixon	OST101 (976626-100/001)	2973

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EXAMINER	
CHENG, JACQUELINE	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
12/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/623,466	DIXON ET AL.	
	Examiner	Art Unit	
	JACQUELINE CHENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 8, 2009 has been entered.

Response to Arguments

2. Applicant's amendments have overcome the previous claim objections. Claim objection of claim 44 has been withdrawn.

3. Applicant's arguments with respect to claim 44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claim 57 is objected to because if the bone marker level was not taken then the integrated unit cannot have received the bone marker level.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 44-47, 51-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang'208 (US 2003/0015208 A1) in view of Faulkner (US 6,740,041 B2) further in view of Lang'814 (US 7,184,814 B2).

7. Lang'208 discloses a method of diagnosing bone related diseases where using a combination of several independent measurements or tests provides for greater diagnostic power. One of the measurements is a bone characteristic level such as bone mineral density (paragraph 0030) taken using systems such as X-ray, ultrasound, MRI or CT (paragraph 0027). Lang'208 does not explicitly disclose using a T-score as a measure of the bone mineral density, however it is well known in the art as disclosed by Faulkner that a raw bone mineral density value has limited meaning to a physician (col. 1 line 27-35) so it is obvious to provide an established reference such as a T-score to make the raw bone mineral density value of Lang'208 useful.

8. Another one of the measurements that Lang'208 discloses is determining a movement pattern of the joint (paragraph 0047). Lang'208 does not explicitly disclose how movement pattern of a joint is determined so it would be obvious to use a well known method of determining movement pattern of a joint such as disclosed by Lang'814 (col. 13 line 24-28). Lang'814 discloses determining a movement pattern comprises obtaining an external image of the joint such as performing gait analyses including static loading alignments or force plates for measurement of foot-ground reaction forces (col. 31 line 48-67, col. 32 line 30-47).

9. A third measurement that Lang'208 discloses is measurement of biomarkers. The biomarkers of a bone marker concentration can be taken from a body fluid such as urine to

identify bone resorption levels (paragraphs 0026). It is inherent that to measure the bone marker level in a body fluid, the body fluid must be put in a container to be analyzed and to obtain the bone marker level an output must be outputted.

10. Depending on the results of the combination of these tests using a mathematical function, a disease is assessed and a therapy such as a postponement of development of bone loss symptom can be prescribed such as taking a calcium supplement (paragraph 0023, 0069, 0072). Further repeat measurements can then be taken over a period of time, which can be seconds, minutes, hours, days, months, or any interval there between to follow up on the therapy (such every month for 8 months which would result in a series of eight gait analyses) (paragraph 0067).

11. **Claims 48-50, 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang'208 in view of Faulkner in view of Lang'814, and further in view of Chaintreuil (US 6,234,969 B1). Chaintreuil discloses a bone densitometer having a housing for a foot in which a pair of ultrasonic transducers engages the heel at a controlled pressure. The ultrasonic waves that are detected are the used to calculate an quantitative ultrasound index, or a stiffness value (fig. 1, col. 4 line 14-61). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Chaintreuil with Lang'208 as Lang'208 discloses using ultrasound measurements for the imaging test.

12. **Claim 60 and 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang'208 in view of Faulkner in view of Lang'814, and further in view of Pratt (US 4,195,643).

Lang'814 does not explicitly disclose the method of performing the gait analysis, but does disclose that the analysis can be done with loading alignments and force plates (col. 31 line 48-67, col. 32 line 30-47). It would therefore be obvious to one skilled in the art to use any well known measuring and characterizing of gait, in particular one that uses force plates such as disclosed by Pratt. Pratt discloses to measure and characterize gait a person stands on a dual force plate system which determines the force exerted by the right foot and the left foot. These forces can be compared to determine a difference in the forces exerted by each foot, and determine balance forces of the subject (col. 5 line 61-col. 6 line 14, fig. 3). Balance forces of a subject can also be measured with one foot off the ground (col. 9 line 62-65).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768